

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0174]

DMB

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**Agency Information Collection Activities; Submission for OMB Review; Comment Request; FDA Recall Regulations**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**FDA Recall Regulations—Part 7 (21 CFR Part 7 (Subpart C))—(OMB Control Number 0910–0249)—Extension**

Section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371) and part 7, subpart C sets forth the recall regulations (guidelines) and provides guidance to manufacturers on recall responsibilities. The guidelines apply to all FDA-regulated products (i.e., food, including animal feed; drugs, including animal drugs; medical devices, including in vitro diagnostic products; cosmetics; and biological products intended for human use). These responsibilities include development of a recall strategy that requires time by the firm to determine the actions or procedures required to manage the recall (§ 7.42); providing FDA with complete details of the recall including reason(s) for the removal or correction, risk evaluation, quantity produced, distribution information, firm's recall strategy, copy of any recall communication(s), and a contact official (§ 7.46); notifying direct accounts of the recall, providing guidance regarding further distribution, giving instructions as to what to do with the product, providing recipients with a ready means of reporting to the recalling firm (§ 7.49); and submitting periodic status reports so that FDA may assess the progress of the recall. Status report information may be determined by, among other things, evaluating return reply cards, effectiveness checks, and product returns (§ 7.53); and providing the opportunity for a firm to request in writing that FDA terminate the recall (§ 7.55).

A search of the FDA database was performed to determine the number of recalls that took place during fiscal year 2000. The resulting number of recalls from this database search (1,933) is used in estimating the current annual reporting burden for this report. FDA estimates the total annual industry burden to collect and provide the above information to be 157,675 burden hours.

In the **Federal Register** of May 1, 2001 (66 FR 21767), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received on the information collection.

We agree with the comment that the agency is slow in providing the recall classification letter to recalling firms and are taking steps to streamline the classification process which, in turn,

will improve the timeliness of the classification letter. However, we believe that recalling firms are usually aware of the significance of the defect in a recalled product and know the likely FDA classification. This may be based on the firm's own health hazard evaluation, by precedent recalls and information published on FDA's Web sites, and/or by verbal communication with FDA district office recall coordinators. The latter is especially true regarding the classification of serious to potentially life-threatening hazard-to-health recall actions (class I). In such situations, the delivery of a classification letter usually follows extensive communications between recalling firms and FDA in which classification, recall strategy, and press releases are immediately discussed.

We have accepted the commenter's estimate of the time expended to conduct recalls and have used those figures, coupled with revised recall numbers, to develop what we believe to be a more realistic estimate of the time expended by FDA-regulated industry to develop and report recall information requested by FDA.

FDA agrees with the comment to have a process whereby reports and any other necessary information can be submitted by e-mail. In many cases, this has become routine for some firms and FDA district offices. Certainly there is no reason not to use e-mail or facsimile communications in most recall situations; however, FDA would maintain the prerogative for investigational visits and other in-person communications where the agency considers it appropriate. In fact, FDA is currently working toward providing "industry guidance" online which will provide a format for industry responses to recall situations.

At the present time, the names and telephone numbers of FDA's district office recall coordinators may be found on the Internet at [http://www.fda.gov/ora/inspect\\_ref/iom/iomoradir\\_monitors.html#RECALL](http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#RECALL). Unfortunately, this provides information from FDA's latest published location directory and is not always current. We will see that this list is updated if it is possible to do so. Additionally, changes to the FDA Web site's recall information and reporting systems which are currently under development, will maintain an easy to locate, user-friendly recall

section that will include a current listing of all district coordinators that will include names, telephone and facsimile numbers, mail, and e-mail addresses.

At this time, we will refer to the Center for Food Safety and Applied Nutrition your suggestion to allow processing authorities to authorize reconditioning/destruction of thermally processed low acid and acidified foods in hermetically sealed containers and for the recalling firm to then submit a summary of the disposition action to FDA.

As a result of the comment received, the following is a revised summary of the estimated annual burden hours for manufacturers, processors, and distributors to comply with the voluntary reporting requirements of FDA's recall regulations.

Recognizing that there may be a vast difference in the information collection and reporting time involved in different recalls of FDA's regulated products, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
7.42	1,855	1	1,855	15	27,825
7.26 and 7.49	1,855	1	1,855	20	37,100
7.53	1,855	4	7,420	10	74,200
7.55(b)	1,855	1	1,855	10	18,550
Total					157,675

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 8/13/01

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August 13, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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Stephanie Reece